

REMARKS

Status of the Claims

Claims 1-34 are currently pending in the application. Claims 1-9, 22, 23 and 25 stand rejected. Claims 10-21, 24 and 26-33 have been withdrawn in response to a prior restriction requirement. Claims 1, 4, 6 and 22 have been amended as set forth herein. All cancellations and amendments are made without prejudice or disclaimer. New claim 34 has been added. No new matter has been added by way of the present amendments. Specifically, the amendment to claims 1 and 2 are supported by the specification at page 6, lines 22-25 and page 5, line 30 to page 6, line 2. New claim 34 is supported by original claim 22. Reconsideration is respectfully requested.

Objections to the Specification

The Examiner objects to the specification for containing an embedded hyperlink. (*See, Office Action of September 14, 2005, at page 3, hereinafter referred to as “Office Action”*). Appropriate amendment to the specification is presented in the present response. No new matter has been added. Reconsideration and withdrawal of the objection to the specification are respectfully requested.

Sequence Rules

The Examiner states that Table 3, on page 23 of the specification, fails to meet the requirements of 37 C.F.R. § 1.821(a)(1)-(a)(2). While Applicants disagree with the Examiner and maintain that amendment of Table 3 is not necessary, to expedite prosecution, amendment

has been made to the specification such that each of SEQ ID NOS: 22-42 is next to the corresponding primer.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description

Claims 1-8, 22, 23 and 25 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. (*See, Office Action*, at page 4). Applicants traverse the rejection as set forth herein.

The Examiner states that “Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus,” which is believed to encompass full-length genes and cDNAs that are not described and having a “substantial variability among the species of DNAs encompassed within the scope of the claims as evidenced by the variation between closely related primates.” (*Id.* at pages 5-6).

Although Applicants do not agree that claim 1 lacks sufficient written description in the specification, to expedite prosecution, claim 1, as amended, recites: “An isolated, purified DYXC1 nucleic acid selected from the group consisting of: SEQ ID NO:1 or the complement of SEQ ID NO:1, a nucleic acid able to hybridize to SEQ ID NO:1 under stringent conditions, wherein said stringent conditions comprise 6 x NaCl/sodium citrate (SSC) at about 45 °C hybridization and 2 x SSC wash at 50 °C, and a homologue of a SEQ ID NO:1-encoded polypeptide, wherein said homologue is at least 79% homologous to a SEQ ID NO:1-encoded polypeptide, wherein said nucleic acid is genetically linked to dyslexia, and wherein a polypeptide encoded by said isolated, purified DYXC1 nucleic acid localizes to cell nuclei when

expressed *in vivo*.” As amended, claim 1 no longer recites the phrase “SEQ ID NO:1 or a complement thereof; homologs and variants thereof, and fragments thereof.” Furthermore, amended claim 1 is directed to only those nucleic acids able to hybridize to SEQ ID NO:1 under explicitly defined stringent hybridization conditions. Support for this amendment may be found at, for instance, page 6, lines 22-25.

Additionally, the Examiner states that “no common structural attributes identify the members of the genus,” referring to claim 22, which recites “allelic variants thereof” with respect to the *DYX1C1* gene. Although Applicants do not agree that claim 22 lacks sufficient written description support in the specification, to expedite prosecution, claim 22 has been amended to remove the phrase “allelic variants thereof,” thus obviating the rejection as to claim 22.

The Examiner also states that the “specification fails to describe a representative number of nucleic acids which minimally comprise a fragment of SEQ ID NO:1.” As already commented on, above, the phrase “and fragments thereof,” has been removed from claim 1, thus obviating the written description rejection based on the recitation of this phrase in claim 1.

No independent reasoning is provided for the written description rejection of dependent claims 2-8, 23 and 25. Thus, dependent claims are not lacking in written description support for, *inter alia*, depending from an independent claim which also does not lack written description support, claims 1 and 22.

Reconsideration and withdrawal of the written description rejection of claims 1-8, 22, 23 and 25 are respectfully requested.

Enablement

Claims 1-9, 22, 23 and 25 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See, Office Action*, at page 6). Applicants traverse the rejection as set forth herein.

The Examiner states that “while being enabling for an isolated and purified DYXC1 nucleic acid comprising SEQ ID NO:1, 13, 15, 17, 19, and the complements thereof,” the specification “does not reasonably provide enablement for a nucleic acid homolog, variant, fragment or nucleic acid which hybridizes to SEQ ID NO:1.” (*See, Id.* at pages 8-9). Although Applicants do not agree that claims 1 and 22 lack enablement by the specification, to expedite prosecution, claims 1 and 22 have been amended as already discussed, above. The arguments and statements presented in response to the written description rejection are incorporated herein. Thus, at least as amended, claims 1 and 22 do not lack enablement.

Claim 9 recites, “An isolated nucleic acid molecule encoding DYXC1 amino acid sequence of SEQ ID NO:3.” No independent reasoning is provided for the rejection of claim 9 as lacking enablement. Applicants assert that claim 9 is fully enabled for, *inter alia*, fully disclosing the sequence of SEQ ID NO:3 and its function. Amino acid sequence SEQ ID NO:3 is the corresponding translation of nucleic acid sequence SEQ ID NO:1. (*See, Specification*, at page 2, lines 20-30).

No independent reasoning is provided for the written description rejection of dependent claims 2-8, 23 and 25. Thus, dependent claims are not lacking in written description support for, *inter alia*, depending from an independent claim which also does not lack written description support, claims 1 and 22.

Reconsideration and withdrawal of the written description rejection of claims 1-9, 22, 23 and 25 are respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 22, 23 and 25 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. (*See, Office Action*, at page 14). Applicants traverse the rejection as set forth herein.

The Examiner states that claims 22, 23 and 25 are indefinite for reciting the term “preferably.” Claim 22 has been amended to remove the phrase “preferably labeled” to a new dependent claim, claim 34.

No independent reason is given for the rejection of claims 23 and 25. Thus, claims 23 and 25 are not indefinite for, *inter alia*, depending from a definite independent claim, claim 22.

Reconsideration and withdrawal of the indefiniteness rejection of claims 22, 23 and 25 are respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Brennan (U.S. Patent no. 5,474,796)

Claims 1-6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brennan, U.S. Patent No. 5,474,796 (hereinafter referred to as “Brennan”). (*See, Office Action*, at page 15). Applicants traverse the rejection as set forth herein.

The Examiner states that Brennan teaches “oligonucleotides having 10 nucleotides each (10-mers),” wherein at least one of the 10-mers disclosed would “constitute a complement of

SEQ ID NO:1; a fragment of SEQ ID NO:1, and would be a primer probe.” (*See, Id.*). Although Applicants do not agree that Brennan anticipates the present invention, or that “a compliment thereof” would not include “the complement,” claims 1, 4 and 6 have been amended to recite “the complement” as suggested by the Examiner. Thus, Brennan does not anticipate the presently claimed invention because Brennan does not disclose each and every element of the presently claimed invention. Specifically, *inter alia*, Brennan does not disclose “the complement” of SEQ ID NO:1.

Dependent claims 2, 3 and 5 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1-6 are respectfully requested.

NIH-MGC (GenBank Accession Number BE972748)

Claims 1-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by NIH-MGC (GenBank Accession Number BE972748) (hereinafter referred to as “sequence ‘748”). (*See, Id.* at page 15). Applicants traverse the rejection as set forth herein.

The Examiner states that sequence ‘748 is 100% identical over nucleotides 686-1049 of SEQ ID NO:1. (*Id.*). As previously discussed, above, claim 1 has been amended to recite, in part, “An isolated, purified DYXC1 nucleic acid selected from the group consisting of: SEQ ID NO:1 or the complement of SEQ ID NO:1.” As amended, claim 1 no longer encompasses “fragments thereof.” Thus, sequence ‘748 does not disclose each and every element of the presently claimed invention and therefore does not anticipate the presently claimed invention.

Dependent claims 2-8 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1-8 are respectfully requested.

Taipale et al. (GenBank Accession No. AF337549)

Claims 1-6 and 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Taipale et al. (GenBank Accession No. AF337549) (hereinafter referred to as “Taipale et al.”). (*See, Id.* at page 16). Applicants traverse the rejection as set forth herein.

The Examiner states that Taipale et al. disclosed nucleic acid EKN1 mRNA from human, which correspond to nucleotides 1-1263 of SEQ ID NO:1 according to the present application, on February 2, 2002. However, the present application claims priority to U.S. Provisional Application Serial No. 60/355,782 filed on February 12, 2002. Thus, Taipale et al. is not available as prior art under 35 U.S.C. § 102(b) as to any claims which are supported by the U.S. provisional application.

Dependent claims 2-6 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1-6 and 9 are respectfully requested.

Applied Biosystems Product Catalog (1993, pages 135-164)

Claims 22, 23 and 25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Applied Biosystems Product Catalog (1993, pages 135-164) (hereinafter referred to as “ABP”). (*See, Id.*). Applicants traverse the rejection as set forth herein.

The Examiner states that ABP teaches every limitation of the claims. (*Id.* at page 18). However, nowhere in ABP is there disclosed a compound that specifically detects the *DYXC1* gene. At most, ABP provides components from which one of ordinary skill in the art might be able to conduct further experiments enabling that person to eventually discover some compound that may specifically detect the *DYXC1* gene. However, the disclosure of ABP does not provide for a kit, as claimed, which comprises a specific component, capable of detecting *DYXC1* as part of the purchased kit. There are no vials containing compositions containing compounds that specifically detect the *DYXC1* gene. The ABP kit does not contain directions or instructions on how to find a compound that will specifically detect the *DYXC1* gene. At most, ABP presents an invitation to experiment. Such is not the standard for anticipation. Because ABP does not disclose each and every element of claim 22, ABP cannot anticipate claim 22.

Dependent claims 22 and 25 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 22, 23 and 25 are respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 22, 23 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Brennan in view of Ahern, *The Scientist*, 9(15):20, 1995 (hereinafter referred to as “Ahern”). (See, Office Action, at page 19). Applicants traverse the rejection as hereinafter set forth.

M.P.E.P. § 706.02(j) sets forth the standard for establishing a *prima facie* case of obviousness as follows:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

The Examiner states that Brennan does not specifically teach placing the array with instructions into a kit. (*Id.*). The Examiner further states that Ahern cures this defect because Ahern teaches “reagent kits offer scientists good return on investment.” (*Id.*). However, as already discussed, above, with respect to the anticipation rejection, Brennan does not disclose each and every limitation of the presently claimed invention. Thus, Brennan cannot, by itself, provide a basis for a *prima facie* case of obviousness.

Furthermore, the secondary reference of Ahern does not cure this defect. Ahern discloses nothing about SEQ ID NO:1.

Reconsideration and withdrawal of the obviousness rejection of claims 22, 23 and 25 are respectfully requested.

Rejections Under the Obviousness-Type Double Patenting Doctrine

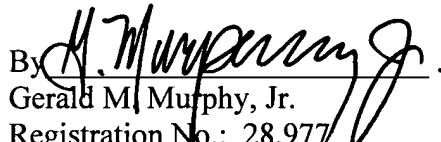
Claims 1-9, 22, 23 and 25 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable by claims 1-9, 22, 23 and 25 of copending U.S. Patent Application Serial No. 10/364,505. It is noted that this is only a provisional rejection and that Applicants do not have to respond to this rejection until the claims of the copending application have been allowed. Applicants are aware of the copending application and note further that an election was made in response to a Restriction Requirement in the copending application. The scope of the subject matter elected in the copending application is not overlapping in scope with the claims elected in the present application.

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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